SC/DHEC REGION 6 PANDEMIC INFLUENZA ETHICS PANEL

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THE THREAT

Major Influenza A Pandemics of the Twentieth Century

Major Years	Subtype	Excess US Mortality
1918-19 "Spanish Flu"	H1N1	550,000 (mortal. < 10%)
'57-'58 Asian	H2N2	70,000
'68-69 Hong Kong	H3N2	36,000 (global > 1m.)
NEXT most likely:	H5N1(Avian)	? 2-5%

The 1918 virus was a direct mutation from avian H5N1 and probably originated in America.

Avian Influenza A-H5N1: Why We Should be More Concerned Now

1. A-H5N1 clade 2, subclade 1 now reported with occas. human-to-human transmission
2. A-H5N1 clade 2 now ~resistant to Tamiflu
3. Recent Indonesian mortality rate↑ >86% !
4. Recent case of maternal-fetal deaths with A-H5N1 clade 2 found in mult. fetal tissues

Sources: 1&2:EID 9.07, 3:pandemicflu.gov→WHO, 4:MedPage 9.28.07

WHO Phases and US Stages of a Pandemic

WHO Phases			US Stages	
Inter-Pandemic Period (New virus in animals, no human cases)	Low risk of human cases	1	0	New domestic animal outbreak in at-risk country
	Higher risk of human cases	2		
Pandemic Alert (New virus causes human cases)	No or very limited human-human transmission	3	1	Suspected human outbreak overseas
	Evidence of increased human-human transmission	4	2	Confirmed human outbreak overseas
	Evidence of significant human-human transmission	5		
Pandemic Period	Efficient and sustained human-human transmission	6	3	Widespread human outbreaks in multiple locations overseas
			4	First human case in North America
			5	Spread throughout US
			6	Recovery and preparation for subsequent waves

PANDEMIC PLANNING
GET INFORMED BE PREPARED

Est. Potential Human Impact of the Next Influenza Pandemic in the US- 2006

Planning Assumptions: Health Care

- 50% or more of those who become ill will seek medical care
- Number of hospitalizations and deaths will depend on the virulence of the pandemic virus

CDC estimates:	Moderate (1957-like)	Severe (1918-like)
Illness 15-25-35% get ill	90 million (30%)	90 million (30%)
Outpatient medical care	45 million (50%)	45 million (50%)
Hospitalization	865,000	9, 900,000
ICU care	128,750	1,485,000
Mechanical ventilation	64,875	745,500
Deaths Mortality rate	209,000 ~0.2%	1,903,000 ~2%

Source: Bruce Gellin, MD, MPH- Dir., Natl. Vax. Program Office, OSAH, US DHHS. 2/06

CDC
Centers for Disease Control and Prevention

Pan Flu: Estimated Disease Impact in SC

- First wave would peak in ~6 wks in a community & last ≥2, ~3-4 months
- Cases statewide: 560,000 – 1,320,000 (first wave)
- Additional hospitalizations: 7,200 – 16,800 (normally no empty beds now in winter)
- **MD office visits: 25 extra/doctor/day**
- Flu deaths: 2,200 – 5,000 (close to double the usual number during the peak of the pandemic
- School children would be the biggest spreaders of infection

Source: DHEC- Tom Fabian, MD, MPH

Pandemic Influenza (worst case): caring for increasing #s of sick citizens- hospitals' surge capacity max'd out.

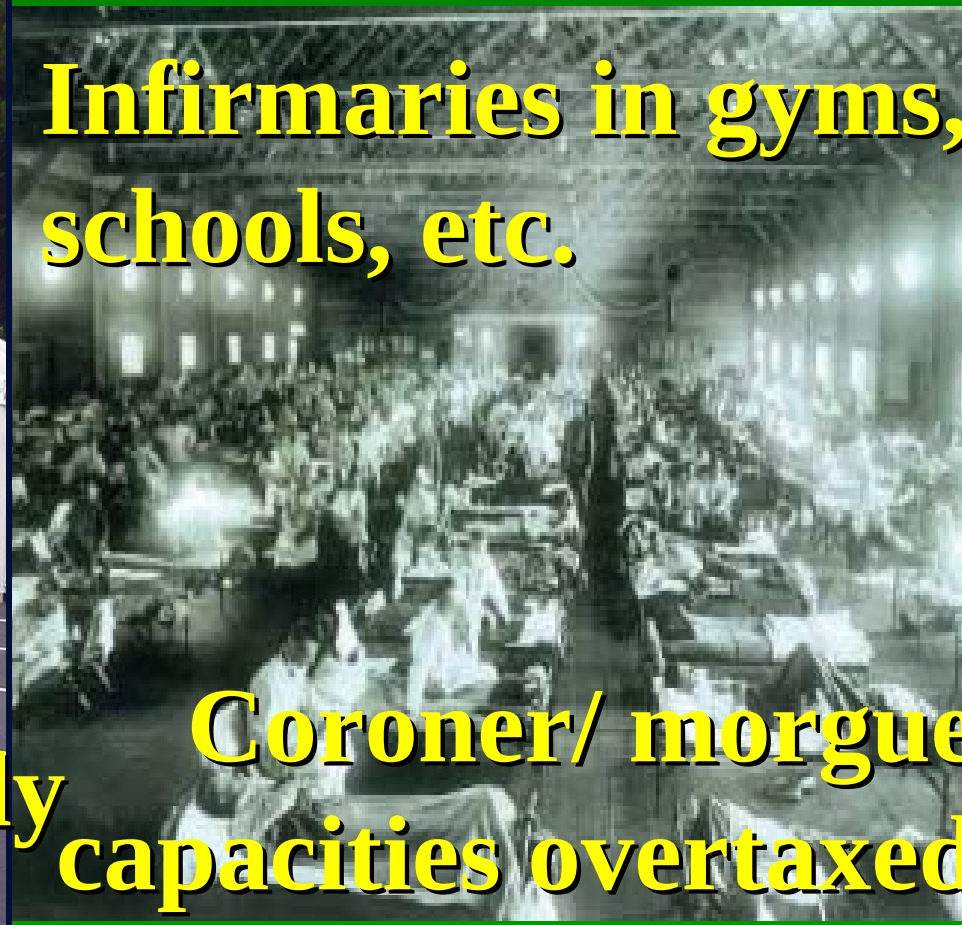

Photo: David Weber MD MPH

THE ETHICS

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PANEL GOALS:

1. **Recommend antiviral distribution priorities**
2. **Recommend vaccine distribution priorities**
3. **Recommend treatment triage priorities**

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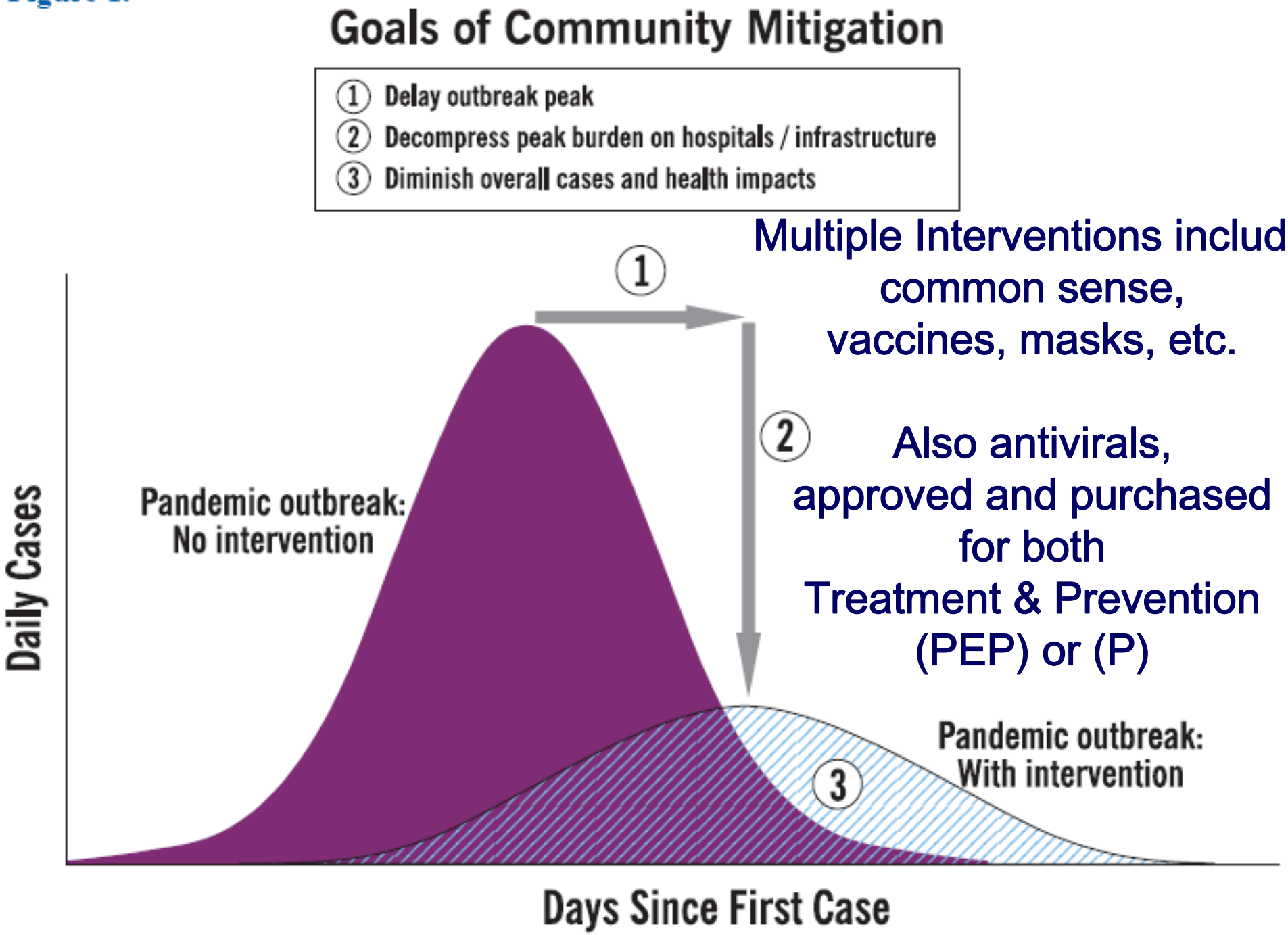
ETHICS PANEL VALUES

- **Maximize the number of Pan Flu survivors**
- **Minimize the rate of PanFlu infection**

Figure 1.


Goals of Community Mitigation
1 Delay outbreak peak
2 Decompress peak burden on hospitals / infrastructure
3 Diminish overall cases and health impacts
Multiple Interventions includ
common sense,
vaccines, masks, etc.
Also antivirals,
approved and purchased
for both
Treatment & Prevention
(PEP) or (P)
1
2
3
Pandemic outbreak:
No intervention
Pandemic outbreak:
With intervention
Daily Cases
Days Since First Case

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- **Substantive Values**
- **Individual Liberty Restrictions**

Movement, Contact, Quarantine, Vaccine, Antiviral, Respirator Recipient Priorities

- **Protection of the Public from Harm**

Reasons for public health measures

- **Proportionality of the above values**

Focus on actual risk and critical needs

- **Privacy Overrides**

Traditional right to privacy may become a subordinate moral value

- **Healthcare Workers' Duty to Provide Care**

Competing professional and personal obligations

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- **Reciprocity for Healthcare Workers**

Social support for burden on patients, health care workers, and families

- **Equity in Various Healthcare Services**

Possible limits on emergency, necessary, or elective medical services

- **Trust between Clinicians, Patients, Public**

Decision makers must balance need, control, and stakeholder trust

- **Solidarity for Institutions and Nations**

Collaborative approaches that set aside national and institutional territoriality

- **Stewardship by Decision Makers**

Governance at all levels using coordinated, ethical, and reasonable decision making

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GOALS OF TREATMENT PRIORITIES

- **Treating as many patients as possible**
- **Applying treatment resources to those most likely to benefit**
- **Involving hospital ethics committees in local priority decisions**
- **Establishing triage guidelines in advance with wide public communication during pandemic waves**

THE RESPONSE

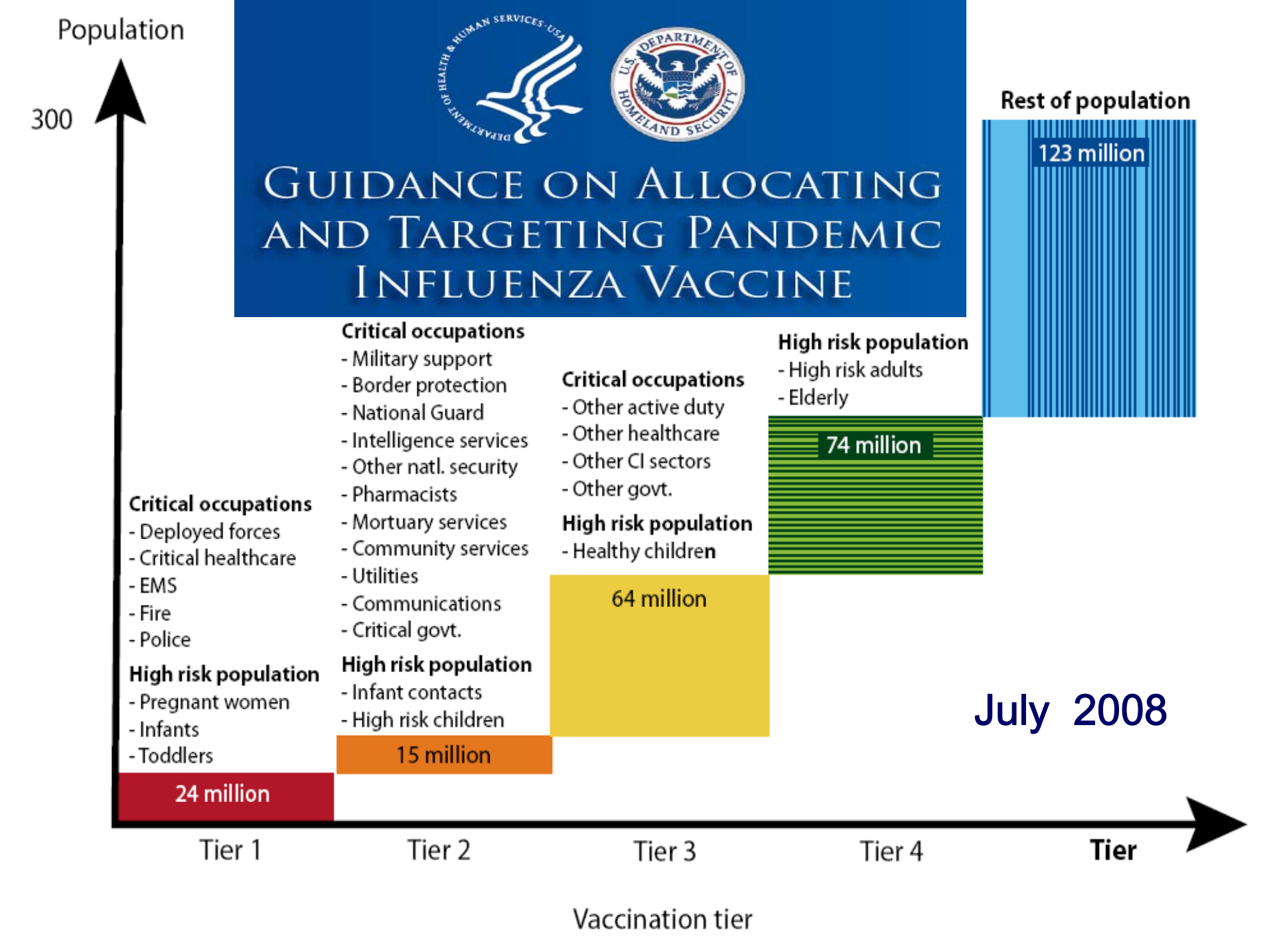
ACIP/NVAC proposed vaccine priority group recommendations

Q: if/how much the currently-stockpiled A-H5N1 vaccine will match the next Pan Flu strain ?

Novel virus→ ~6-7 mos. to develop a novel vaccine

1A	Vaccine and antiviral manufacturers; HCW ←	(8M)
1B	Highest risk	(16M)
1C	Pregnant women HH contacts*	(11M)
1D	PH emergency workers Key government officials	(?)
2A	High risk	(58M)
2b	Public safety and other critical infrastructure	(9M)
3	Other key health decision makers; funeral services	(?)
4	Healthy children and adults	(180M)

* Of severely immunocompromised and infants <6m


Population
300
GUIDANCE ON ALLOCATING AND TARGETING PANDEMIC INFLUENZA VACCINE
Rest of population
123 million
High risk population
- High risk adults
- Elderly
74 million
Critical occupations
- Other active duty
- Other healthcare
- Other CI sectors
- Other govt.
High risk population
- Healthy children
64 million
Critical occupations
- Military support
- Border protection
- National Guard
- Intelligence services
- Other natl. security
- Pharmacists
- Mortuary services
- Community services
- Utilities
- Communications
- Critical govt.
High risk population
- Infant contacts
- High risk children
15 million
Critical occupations
- Deployed forces
- Critical healthcare
- EMS
- Fire
- Police
High risk population
- Pregnant women
- Infants
- Toddlers
24 million
July 2008
Tier 1
Tier 2
Tier 3
Tier 4
Tier
Vaccination tier

Pan Flu: SNS Antiviral Allocation: Tx (T) of Patients with ILI

Table D-2: Antiviral Drug Priority Group Recommendations* National Plan, Appendix D (Nov. '05)

	Group	Estimated population (millions)	Strategy**	# Courses (millions)		Rationale
				For target group	Cumulative	
1	Patients admitted to hospital***	10.0	T	7.5	7.5	Consistent with medical practice and ethics to treat those with serious illness and who are most likely to die
2	Health care workers (HCW) with direct patient contact and emergency medical service (EMS) providers[4]	9.2	T	2.4	9.9	Healthcare workers are required for quality medical care. There is little surge capacity among healthcare sector personnel to meet increased demand.
3	Highest risk outpatients—immunocompromised persons and pregnant women	2.5	T	0.7	10.6	Groups at greatest risk of hospitalization and death; immunocompromised cannot be protected by vaccination.
4	Pandemic health responders (public health, vaccinators, vaccine and antiviral manufacturers), public safety (police, fire, corrections), and government decision-makers	3.3	T	0.9	11.5	Groups are critical for an effective public health response to a pandemic.
5	Increased risk outpatients—young children 12-23 months old, persons ≥ 65 yrs old, and persons with underlying medical conditio	85.5	T	22.4	33.9	Groups are at high risk for hospitalization and death.

T = Tx = 1 cap. bid x 5 d.

pandemicflu.gov→ federal plans→ HHS Pan Flu Strategic Plan

Pan Flu: SNS Antiviral Allocation: PEP, P,& T of Patients & HCWs

Table D-2: Antiviral Drug Priority Group Recommendations*

National Plan, Appendix D (11-05)

	Group	Estimated population (millions)	Strategy**	# Courses (millions)		Rationale
				For target group	Cumulative	
6	Outbreak response in nursing homes and other residential settings	NA	PEP	2.0	35.9	Treatment of patients and prophylaxis of contacts is effective in stopping outbreaks; vaccination priorities do not include nursing home residents
7	HCWs in emergency departments, intensive care units, dialysis centers, and EMS providers	1.2	P	4.8	40.7	These groups are most critical to an effective healthcare response and have limited surge capacity. Prophylaxis will
8	Pandemic societal responders (e.g., critical infrastructure groups as defined in the vaccine priorities) and HCW without direct patient contact	10.2	T	2.7	43.4	infrastructure groups that have impact on maintaining health, implementing a pandemic response, and maintaining societal functions
9	Other outpatients	180	T	47.3	90.7	Includes others who develop influenza and do not fall within the above groups
10	Highest risk outpatients	2.5	P	10.0	100.7	Prevents illness in the highest risk groups for hospitalization and death.
11	Other HCWs with direct patient contact	8.0	P	32.0	132.7	Prevention would best reduce absenteeism and preserve critical [illegible]

PEP or P = 1 cap. qd x 5+ days

These groups are NOT mutually exclusive or timeline-defined!

Most HCWs fall in Tier 11 !

pandemicflu.gov→ federal plans→ HHS Pan Flu Strategic Plan

ICU TRIAGE PROTOCOL

Canadian Medical Association Journal

QUALIFICATIONS FOR ICU ADMISSION

- **Inclusion Criteria: Patients who may benefit from ICU care and who have a high priority of survival upon hospital discharge**

  (Includes influenza patients who require ventilator support or exhibit clinical evidence of shock and require treatment in an ICU setting.)

ICU TRIAGE PROTOCOL

Canadian Medical Association Journal

QUALIFICATIONS FOR ICU ADMISSION

- **Exclusion Criteria: Conditions that would rule out an ICU admission (e.g., 85 yrs old, end-stage organ failure, metastatic cancer, severe trauma or burns)**

  (Patients that are likely to have a poor chance of survival with or without ICU care and would potentially tie up resources that could be used for patients who have a greater chance of recovery.)

ICU TRIAGE PROTOCOL

Canadian Medical Association Journal

PRIORITIZATION FOR ICU ADMISSION

- **BLUE CODE: Patients not to be admitted as they do not meet the inclusion criteria – to be medically managed, provided palliative treatment, and discharged from the ICU**
- **RED CODE: Patients with the highest priority of ICU resources – sick enough to require the resource and whose outcome would be poor if they do not receive it and who are likely to recover with ICU care**

ICU TRIAGE PROTOCOL

Canadian Medical Association Journal

PRIORITIZATION FOR ICU ADMISSION

- **YELLOW CODE: Patients will receive ICU care if available, but not at the expense of a RED CODE patient**
- **GREEN CODE: Patients deemed not ill enough to require ICU care**

Pandemic Flu: Ethical Issues

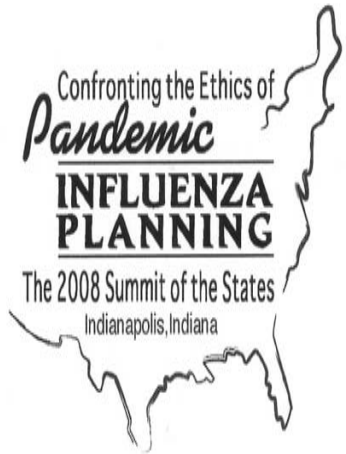
- Allocating limited/ scarce resources (AVs, PPE, etc)
- Altered (alternative) standards of care (ICU, vents, etc)
- Protecting HCWs and Household contacts (Post-Exposure Prophylaxis [PEP], masks/ other PPE)
- Protecting the public: Isolation & Quarantine, etc?
- Medico-legal protection (provider indemnification)
- Informing the public: best messages? by whom?
- US Ethical Summit of States 7.08→ SC Committee forming in 2008

THE ACTIONS

Indiana State Department of Health

astho™

INDIANA UNIVERSITY
CENTER FOR BIOETHICS



Confronting the Ethics of Pandemic Influenza Planning: Communiqué from the 2008 Summit of the States

Indianapolis, Indiana
July 14-15, 2008

1. Key Ethical Challenges that States and Territories Face in Planning for Pandemic Influenza

- Meeting the obligation to engage communities in planning and response to ensure fairness, transparency and participation
- Identifying and defining criteria for allocation of scarce health care and critical infrastructure resources
- Defining criteria and mechanisms for implementing altered standards and places of care
- Preventing exacerbation of disparities in access to care
- Balancing the rights and duties of health care and critical infrastructure workers
- Providing palliative care
- Meeting the needs of at-risk populations
- Assuring that community mitigation and containment strategies are appropriate for the severity of the pandemic
- Respecting cultural and religious practices in the face of mass fatalities

THE ETHICS OF PANDEMIC INFLUENZA PLANNING

SUMMIT OF THE STATES

Indianapolis, July 14-15, 2008

KEY ETHICAL CHALLENGES:

***Engage communities in planning to ensure fairness and transparency**

***Define criteria for allocating scarce health care resources**

***Define criteria and mechanisms for altered standards and places of care**

***Prevent exacerbation of disparities in access to care**

***Balance the rights and duties of health care and critical infrastructure workers**

***Provide palliative care**

***Meet the needs of at-risk populations**

***Assure that community mitigation and containment strategies are appropriate**

***Respect cultural and religious practices in the face of mass fatalities**

SC Pandemic Influenza Ethics: Some Planning Action Topics

- **Altered standards of medical care during disasters**

  Emergency Department triage, ICU admission and discharge criteria, outpatient care, home care, palliative care

- **Prioritization (rationing) of limited/ scarce resources**

  Ventilators, bed space, antivirals, prophylactics, vaccines

- **Implementing and communicating necessary restrictions/ limitations on personal freedoms**

  Quarantine, isolation, school/church closures, social distancing

- **Medico-legal issues**

  State Board of Medical Examiners approval of altered standards of care,

  Legislature: legislation needed providing narrowly circumscribed legal indemnification of triage officers and other medical providers implementing altered standards of care

- **Other**

  Role of hospital ethics committees, mandating restrictions and requirements on medical staff privileges, volunteer healthcare workers, home care mechanisms

IMPLEMENTATION TIMELINE

1. **(2008-2009) Convene a SC Pandemic Influenza Ethics Committee, hold regular meetings, draft guidelines of alternative standards of care and triage medical definitions**

   Involving SCMA, SC Board of Medical Examiners, SCHA, SCNA, SCBoN, EMD, EMS, universities, faith communities, citizens groups, print and broadcast media

2. **(2009) Promulgate "Alternative Standards of Care During Disasters" to the State Medical Board for approval, to complement the SC Medical Practice Act**

3. **(2010) Development of a consensus bill for key legislators to introduce and pass in the General Assembly**

   Indemnification (not blanket immunity) for physicians, hospitals, and other providers implementing altered standards of care and rationing scarce resources

Thank you.

Questions?

Recommendations?